REMARKS

In Response to the Restriction Requirement of September 27, 2001, Applicant elected the Claims in Group I with traverse. Also, in this Response mailed December 18, 2001, Applicant cancelled Claims 12-16 and added new Claims 17-21, in order to correct a numbering error in the application as originally filed. As Applicant indicated in the Response to the Restriction Requirement, there was no Claim 12 in the application as originally filed (*i.e.*, the application was originally filed with Claims 1-11, and 13-16). Thus, Applicant submits that by canceling Claims 12-16 and adding Claims 17-21, Applicant was in compliance with 37 C.F.R. 1.126, as the original numbering of the Claims was preserved and the new Claims added in the Response to the Restriction Requirement began with the next consecutive number (*i.e.*, Claim 17). Thus, Applicant respectfully submits that the Claims as filed and indicated in the Response to the Restriction Requirement were correct. Thus, Claims 1-7, 9-11 and 17-21 were pending. However, as the Examiner reiterated the Claim numbering objection, Applicant amended Claims 17-21 to Claims 16-19. Thus, Claims 1-7, 9-11 and 16-19 were pending. In the present Response, Applicant has cancelled Claims 2 and 18 without prejudice. Thus, the pending Claims are 1, 3-7, 9-11, 16-17, and 19.

Applicant appreciates the Examiner's withdrawal of the previous rejections and objections. Applicant herein addresses the Examiner's rejections of Claims 1-7, 9-11 and 16-29 under 35 U.S.C. §112, first paragraph.

1) The Written Description Requirement is Met

The Examiner first argues that the present application does not meet the written description requirement. In particular, the Examiner argues that the present Specification does not provide any additional "representative species by any identifying characteristics or properties other than the 'functionality' of encoding a polypeptide with an inactivated SP1 proteolytic activity and fails to

provide any structure:function correlation present in all members of the claimed genus." (Office Action, page 3). Applicant must respectfully disagree with the Examiner's argument and rationale, as the present Specification teaches how to produce mutated SP1 (serine protease 1) (*See e.g.*, pages 8-9 of the Specification), as well as how to determine whether the mutated SP1 fails within the Claims (*See e.g.*, pages 5-7 of the Specification), and methods for detecting homologues of *B. subtilis* SP1 (and other serine proteases) (*See e.g.*, pages 5-7 of the Specification), and methods for determining protease activity (*See e.g.*, pages 12-13 of the Specification). Applicant respectfully submits that both the structure and function of the mutant SP1s claimed are provided in the Specification, as the amino acid sequence (base structure) and function (protease activity) are well-described throughout the Specification.

Nonetheless, in order to further the prosecution of the present application and Applicant's business interests, yet without acquiescing to the Examiner's argument, Applicant has cancelled Claims 2 and 18, and amended independent Claim 1 to recite that the organism is a member of the genus *Bacillus*. No new matter is added by this amendment. As Claim 11 already includes this limitation, Claim 11 has not been amended. Applicant reserves the right pursue the originally filed, previously amended, and/or similar or broader Claims in subsequent application(s). Applicant respectfully requests that this rejection be withdrawn and the Claims be passed to allowance.

2) The Claims are Enabled

The Examiner has rejected Claims 1-7, 9-11 and 16-19, as allegedly being non-enabled. Applicant must respectfully disagree. The Examiner argues that ". . . despite knowledge in the art for the isolation of nucleic acid molecules, the specification fails to provide guidance regarding how to make a gram-positive microorganism having a mutation or deletion of part or all of SEQ ID NO:1 resulting in SP1 proteolytic activity." (Office Action, page 4). Applicant must respectfully disagree. Indeed, at pages 8-9, the Specification teaches how such

mutations and deletions may be made. Furthermore, the Specification indicates that the S9 protease group, to which the present SP1 belongs contain a catalytic residue triad "Ser-Asp-His" and conserved amino acids around them. Thus, Applicant submits that there is more than sufficient support in the Specification for the Claims. Furthermore, in a previous Office Action mailed January 3, 2002, the Examiner admits that the Specification is "enabling for the nucleic acid encoding serine protease of SEQ ID NO:1" (page 4).

Applicant further submits that there is no requirement that the Claims be limited to "regions of the SP1 (SEQ ID NO:1) structure which may be modified to inactivate SP1 proteolytic activity"; "the general tolerance of to [sic] modification and extent of such tolerance; nor "a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function." Furthermore, as indicated above, Applicant provides information regarding the function of the SP1, and indicates the structure associated with the enzyme's catalytic activity. Thus, Applicant submits that more than sufficient support for the Claims is provided in the Specification.

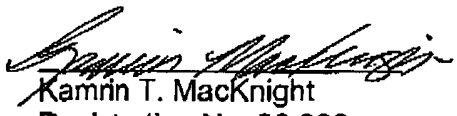
Applicant also must disagree with the Examiner's statement that ". . . it is not routine in the art to screen for modifications . . ." (Office Action, page 4). Applicant further submits that the present Specification teaches how to determine the activity of mutant SP1 enzymes produced according to the presently claimed invention. Thus, the activity of the mutant enzymes can be determined without the requirement of determining the specific amino acid modifications. However, it is contemplated that determination of the specific amino acid modifications may also be used. As Applicant has provided information regarding the SP1 sequence, the sequence of the catalytic triad, the source of the organism, methods for determining proteolytic activity of mutant enzymes, and other information regarding the claimed invention, Applicant respectfully submits that the Claims are enabled. Thus, Applicant submits that the Claims are allowable and respectfully requests that they be passed to allowance.

CONCLUSION

All grounds of rejection in the Office Action of August 29, 2002, having been addressed, reconsideration of the application is respectfully requested. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned.

Respectfully submitted,

Dated: November 26, 2002



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APPENDIX I
MARKED-UP VERSION OF SPECIFICATION'S REPLACEMENT PARAGRAPHS AND REWRITTEN, ADDED, AND/OR CANCELLED CLAIMS

The following is a marked-up version of the Specification's replacement paragraphs pursuant to 37 C.F.R. §1.121(b), as well as a marked-up version of the Claims pursuant to 37 C.F.R. §1.121 (c)(1)(ii) with instructions and markings showing changes made herein to the previous version of record of the Specification and Claims. Underlining denotes added text while bracketing denotes deleted text.

Please cancel Claims 2 and 18.

1. (Twice Amended) A <u>member of the genus *Bacillus*</u> [gram-positive microorganism] having a mutation or deletion of part or all of the gene encoding serine protease 1 (SP1), wherein said gene encoding serine protease 1 comprises SEQ ID NO:1, said mutation or deletion resulting in the inactivation of the SP1 proteolytic activity.

3. (Twice Amended) The microorganism according to Claim [2] <u>1</u>, wherein the member is selected from the group consisting of *B. licheniformis, B. lentus, B. brevis, B. stearothermophilus, B. alkalophilus, B. amyloliquefaciens, B. coagulans, B. circulans, B. lautus* and *Bacillus thuringiensis*.

19. (Twice Amended) The microorganism of Claim [18] <u>1</u>, further comprising a mutation or deletion in at least one of the genes encoding apr, npr, epr, wpr and mrp.